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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,512	03/14/2001	Kayode A. Williams	UOM 0193 PUS	4539

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EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,512

Applicant(s)

WILLIAMS ET AL.

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-31 is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments, see Paper #12, filed 8/4/03, with respect to the rejection(s) of claim(s) 1-3, 6, and 10 under 35 U.S.C. 102(e) and the rejection(s) of claims 5, 7-9, and 11-23 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Khorsandian et al (US 5146913) over.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khorsandian et al (US 5146913) in view of Fukunaga et al (US 6003511).

4. **As to claim 1**, Khorsandian teaches a medical pacifier **32** for delivering gas to a patient, the pacifier comprising a nipple member **48** adapted to be received within an oral cavity of the patient, the nipple member having a conduit extending therethrough and an outlet opening **See Fig. 3A** provided therein; and a base **38** attached to the nipple member and adapted to remain outside the oral cavity, the base including an inlet opening (see Figure 3A) provided therein and a lumen **See Fig. 3A** extending

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therethrough which is in fluid communication with the conduit of the nipple member, wherein the inlet opening **58** for receiving a standard breathing tube on an outer surface of the inlet opening, the breathing tube remaining external to the body such that gas can flow through the base and the nipple member for delivery via the outlet opening into the oral cavity of the patient. Khorsandian fails to explicitly teach the outer diameter of the inlet opening. However, Fukunaga does teach that a 15 mm diameter tube is desirable for pediatric use. Therefore, it would have been obvious for one of ordinary skill in the art to make the outer diameter of the inlet opening of Khorsandian to be 15 mm in diameter so that a tube for a pediatric patient may be connected to the inlet opening since the Khorsandian device is for pediatric use.

5. **As to claim 2**, Khorsandian teaches a medical pacifier wherein the base includes a base plate disposed generally perpendicular to a longitudinal axis of the nipple member, the base plate having a concave front surface facing the nipple member and a convex rear surface facing away from the nipple member.

6. **As to claim 3**, Khorsandian teaches a medical pacifier wherein the base further includes a connector **See Fig 3A** projecting from the rear surface of the base plate, wherein the lumen extends through the connector and the inlet opening is disposed in a proximal end of the connector.

7. **As to claim 5**, Khorsandian teaches essentially all of the limitations except for the specific shape of the connector. However, Applicant has not set forth how the particular limitation solves a stated problem or is advantages over the prior art, or

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provides an unexpected result. Therefore, the connector of Khorsandian would perform equally as well.

8. **As to claim 6**, Khorsandian teaches a medical pacifier wherein the outlet opening is provided in a distal end of the nipple member.

9. **As to claim 7**, pacifiers with a handle ring pivotally attached to the rear surface of the base plate are known in the art (see cited references).

10. **As to claim 9**, pacifiers wherein the nipple member is impregnated with medication are known in the art (see cited references).

11. **As to claim 10**, Khorsandian teaches a medical pacifier wherein the pacifier is molded from a plastic material (**See Col. 4, lines 63-64**).

12. **As to claim 11**, Khorsandian teaches essentially all of the limitations except for wherein the pacifier is of one-piece construction. However, such a construction is known in the art (see cited references).

13. **As to claim 12**, Khorsandian teaches a medical pacifier **32** for delivering gas to a patient, the pacifier comprising a base **38** adapted to remain outside an oral cavity of the patient, the base having a generally concave front surface and a generally convex rear surface, a connector **See Fig. 3A** projecting from the base rear surface which includes an inlet opening **58** provided in a proximal end thereof and a lumen **See Fig. 3A** extending therethrough; a nipple member **48** projecting from the base front surface adapted to be received within an oral cavity of the patient, the nipple member having a conduit extending therethrough which is in fluid communication and an outlet opening provided in a distal end thereof such that anesthetic gas can flow through the pacifier for

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delivery via the outlet opening into the oral cavity of the patient. Khorsandian fails to explicitly teach the outer diameter of the connector proximal end. However, Fukunaga does teach that a 15 mm diameter tube is desirable for pediatric use. Therefore, it would have been obvious for one of ordinary skill in the art to make the outer diameter of the connector proximal end of Khorsandian to be 15 mm in diameter so that a tube for a pediatric patient may be connected to the inlet opening since the Khorsandian device is for pediatric use.

14. Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khorsandian in view of Stevens (US 5810000).

15. **As to claim 8**, Khorsandian teaches essentially all of the limitations except for wherein the pacifier includes a longitudinal slit formed therein for receiving an endoscope. However, Stevens teaches a longitudinal slit formed in a pacifier to introduce an endotracheal tube for ventilating, anesthetizing, or supplying oxygen to infants. Therefore, it would be obvious to one of ordinary skill in the art to modify the pacifier of Khorsandian to include the longitudinal slit of Stevens to introduce an endotracheal tube for ventilating, anesthetizing, or supplying oxygen to infants.

16. Claims 13-16 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hinkle (US 4896666).

17. **As to claim 13**, Hinkle teaches an apparatus for inducing anesthesia in patient, the apparatus comprising a breathing circuit including a source of anesthetic gas **Col. 4, line 57** and a medical pacifier **12** connected to the breathing circuit, the pacifier including a nipple member adapted to be received within an oral cavity of the patient,

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the nipple member having a conduit **34** extending therethrough and an outlet opening **36** provided therein, and a base attached to the nipple member and adapted to remain outside the oral cavity, the base including an inlet opening **40** provided therein and a lumen extending therethrough which is in fluid communication with the conduit of the nipple member, wherein the inlet opening is adapted to be connected to the inlet tube such that anesthetic gas can flow through the base and the nipple member for delivery via the outlet opening into the oral cavity of the patient. Hinkle fails to explicitly recite an inlet tube connected to the source and operable to transport the gas toward the patient, the inlet tube remaining external to the patient. However, the use of an inlet tube connected to a source of gas is well known in the art and it would be obvious to one of ordinary skill in the art to provide a means to carry the gas from the gas source to the patient.

18. **As to claim 14**, Hinkle teaches an apparatus wherein the base includes a base plate **14** disposed generally perpendicular to a longitudinal axis of the nipple member, the base plate having a concave front surface facing the nipple member and a convex rear surface facing away from the nipple member (**See Col. 5, lines 16-18**).

19. **As to claim 15**, Hinkle teaches a medical pacifier wherein the base further includes a connector **50** projecting from the rear surface of the base plate, wherein the lumen extends through the connector and the inlet opening is disposed in a proximal end of the connector.

20. **As to claim 16**, Hinkle teaches essentially all of the limitations except for the specific dimensions of the connector. However, Fukunaga does teach that a 15 mm

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diameter tube is desirable for pediatric use. Therefore, it would have been obvious for one of ordinary skill in the art to make the outer diameter of the connector of Hinkle to be 15 mm in diameter so that a tube for a pediatric patient may be connected to the connector since the Hinkle device is for pediatric use and can be used in conjunction with other respiration functions as disclosed by Hinkle.

21. **As to claim 18**, Hinkle teaches essentially all of the limitations except for the specific shape of the connector. However, Applicant has not set forth how the particular limitation solves a stated problem or is advantages over the prior art, or provides an unexpected result. Therefore, the connector of Hinkle would perform equally as well.

22. **As to claim 19**, Hinkle teaches an apparatus wherein the outlet opening is provided in a distal end of the nipple member.

23. **As to claim 20**, pacifiers with a handle ring pivotally attached to the rear surface of the base plate are known in the art (see cited references).

24. **As to claim 22**, pacifiers wherein the nipple member is impregnated with medication are known in the art (see cited references).

25. **As to claim 23**, Hinkle teaches essentially all of the limitations except for wherein the pacifier is of one-piece construction. However, such a construction is known in the art (see cited references).

26. Claims 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hinkle in view of Gross (US 5823184).

27. **As to claim 17**, Hinkle fails to specifically teach a breathing circuit which includes an outlet tube connected to the source, and the inlet tube and the outlet tube

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being joined to form a single tube end adapted to fitted over the proximal end of the connector. However, Gross does teach a breathing circuit with an outlet tube connected to the source with the inlet and outlet tube being joined to form a single tube in order to provide an uncluttered surgical field and a less bulky breathing circuit. Therefore, it would have been obvious to one of ordinary skill in the art to replace the breathing circuit of Hinkle with that of Gross in order to provide an uncluttered surgical field and a less bulky breathing circuit.

28. Claims 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hinkle in view of Stevens (US 5810000).

29. **As to claim 21**, Hinkle teaches essentially all of the limitations except for wherein the pacifier includes a longitudinal slit formed therein for receiving an endoscope. However, Stevens teaches a longitudinal slit formed in a pacifier to introduce an endotracheal tube for ventilating, anesthetizing, or supplying oxygen to infants. Therefore, it would be obvious to one of ordinary skill in the art to modify the pacifier of Hinkle to include the longitudinal slit of Stevens to introduce an endotracheal tube for ventilating, anesthetizing, or supplying oxygen to infants since Hinkle does disclose the pacifier to be used in conjunction with other respiratory functions.

Allowable Subject Matter

30. Claims 24-31 are allowed over the prior art of record.

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Conclusion

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6626168, US 6125847, US 5765558, US 5685291, US 5640951, US 5121746, US 2693182, and US 1592345.

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

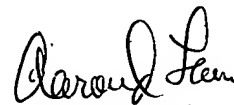
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Aaron J. Lewis
Primary Examiner

mbp